



Goldenseal Root Powder TR 562

Under the conditions of these 2-year feed studies, there was *clear evidence of carcinogenic activity* of goldenseal root powder in male F344/N rats based on the increased incidences of hepatocellular adenoma and hepatocellular adenoma or carcinoma (combined). There was *clear evidence of carcinogenic activity* of goldenseal root powder in female F344/N rats based on the increased incidence of hepatocellular adenoma. There was *some evidence of carcinogenic activity* of goldenseal root powder in male B6C3F1 mice based on the increased incidences of hepatoblastoma and multiple hepatocellular adenoma. There was *no evidence of carcinogenic activity* of goldenseal root powder in female B6C3F1 mice exposed to 3,000, 9,000, or 25,000 ppm goldenseal root powder in feed for 2 years.

Administration of goldenseal root powder resulted in decreased incidences of nonneoplastic lesions in the liver of male and female rats and male mice.



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Androstenedione TR 560

Under the conditions of these 2-year gavage studies, there was *equivocal evidence of carcinogenic activity* of androstenedione in male F344/N rats based on increased incidences of alveolar/bronchiolar adenoma and alveolar/bronchiolar adenoma or carcinoma (combined). There was *equivocal evidence of carcinogenic activity* of androstenedione in female F344/N rats based on increased incidences of mononuclear cell leukemia. There was *clear evidence of carcinogenic activity* of androstenedione in male B6C3F1 mice based on increased incidences of liver neoplasms, **particularly multiple adenomas and carcinomas, and hepatoblastomas**. There was *clear evidence of carcinogenic activity* of androstenedione in female B6C3F1 mice based on increased incidences of hepatocellular adenoma and hepatocellular carcinoma. Increased incidences of pancreatic islet adenoma in male and female mice were also considered chemical related.

Androstenedione administration caused increased incidences in nonneoplastic lesions of the liver in male and female rats and mice; pancreatic islets and exocrine pancreas of female rats; and clitoral gland, kidney, and submandibular salivary gland of female mice.

Decreases in the incidences of testicular interstitial cell adenoma and mononuclear cell leukemia in male rats, mammary gland fibroadenoma, cysts, and hyperplasia in female rats, and malignant lymphoma in female mice were considered related to androstenedione administration.



2,3',4,4',5-Pentachlorobiphenyl (PCB 118) - TR 559

Under the conditions of this 2-year gavage study, there was *clear evidence of carcinogenic activity* of PCB 118 in female Harlan Sprague-Dawley rats based on increased incidences of neoplasms of the liver (cholangiocarcinoma, hepatocholangioma, and hepatocellular adenoma) and cystic keratinizing epithelioma of the lung. Occurrences of carcinoma in the uterus were considered to be related to the administration of PCB 118. Occurrences of squamous cell carcinoma of the uterus and acinar neoplasms of the pancreas may have been related to administration of PCB 118.

Administration of PCB 118 caused increased incidences of nonneoplastic lesions in the liver, lung, adrenal cortex, pancreas, thyroid gland, nose, and kidney.



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3,3',4,4' -Tetrachloroazobenzene (TCAB) - TR 558 - Rats

Under the conditions of these 2-year gavage studies, there was *clear evidence of carcinogenic activity* of TCAB in male Harlan Sprague-Dawley rats based on increased incidences of cystic keratinizing epithelioma of the lung, cholangiocarcinoma of the liver, and gingival squamous cell carcinoma of the oral mucosa. The increased incidences of follicular cell adenoma of the thyroid gland were also considered to be related to TCAB administration. The marginally increased incidence of malignant schwannoma may have been related to TCAB administration.

There was *clear evidence of carcinogenic activity* of TCAB in female Harlan Sprague-Dawley rats based on increased incidences of cystic keratinizing epithelioma of the lung and gingival squamous cell carcinoma of the oral mucosa. The increased incidences of cholangiocarcinoma of the liver and squamous cell papilloma or squamous cell carcinoma (combined) of the forestomach were also considered to be related to TCAB administration. The marginally increased incidences of adenoma of the adrenal cortex may have been related to TCAB administration.



TCAB TR 558 - Mice

There was *clear evidence of carcinogenic activity* of TCAB in male B6C3F1 mice based on increased incidences of transitional epithelial gland carcinoma of the urethra and alveolar/bronchiolar neoplasms of the lung. The increased incidences of squamous cell carcinoma of the forestomach were also considered to be related to TCAB administration.

There was *clear evidence of carcinogenic activity* of TCAB in female B6C3F1 mice based on increased incidences of **fibrosarcoma and fibrosarcoma or malignant schwannoma (combined)** of the skin. The increased incidences of transitional epithelial gland carcinoma of the urethra, alveolar/bronchiolar neoplasms and cystic keratinizing epithelioma of the lung, and squamous cell carcinoma of the forestomach were also considered to be related to TCAB administration. The marginally increased incidences of malignant lymphoma may have been related to TCAB administration.



TR 558 TCAB - Nonneoplastic lesions

TCAB administration caused increased incidences of nonneoplastic lesions of the lung, liver, oral mucosa, forestomach, adrenal cortex, pancreas, blood vessel, spleen, and mesenteric lymph node in male and female rats; the thyroid gland and testis in male rats; the nose in female rats; the urinary bladder, forestomach, glandular stomach, skin, spleen, thymus, liver, and heart in male and female mice; the urethra, ureter, and blood vessel in male mice; and the lung, clitoral gland, ovary, and bone marrow in female mice.



β -Myrcene TR 557

Under the conditions of these 2-year gavage studies, there was *clear evidence of carcinogenic activity* of β -myrcene in male F344/N rats based on increased incidences of renal tubule neoplasms. There was *equivocal evidence of carcinogenic activity* of β -myrcene in female F344/N rats based on increased incidences of renal tubule adenoma. There was *clear evidence of carcinogenic activity* of β -myrcene in male B6C3F1 mice based on increased incidences of hepatocellular adenomas, hepatocellular carcinomas and hepatoblastomas. There was *equivocal evidence of carcinogenic activity* of β -myrcene in female B6C3F1 mice based on marginally increased incidences of hepatocellular adenomas and carcinomas.

Administration of β -myrcene induced nonneoplastic lesions in the kidney of male and female rats, nose of male rats, and liver of male and female mice.



Tetralin TR 561

Under the conditions of these 2-year inhalation studies, there was *some evidence of carcinogenic activity* of tetralin in male F344/N rats based on the increased incidence of cortical renal tubule adenoma. The increased incidence of testicular interstitial cell adenoma may have been related to tetralin exposure. There was *some evidence of carcinogenic activity* of tetralin in female F344/N rats based on the increased incidences of hepatocellular neoplasms (adenomas and adenomas or carcinomas combined) and uterine stromal polyp. There was *no evidence of carcinogenic activity* of tetralin in male B6C3F1 mice exposed to 30, 60, or 120 ppm. There was *equivocal evidence of carcinogenic activity* of tetralin in female B6C3F1 mice based on the increased incidence of splenic hemangiosarcoma.

Exposure to tetralin resulted in nonneoplastic lesions of the nose in male and female rats and mice, kidney and testis in male rats, uterus in female rats, and urinary bladder in male and female mice.